IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC., Plaintiffs, v. ACTAVIS ELIZABETH LLC, ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action No. 17-205-CFC

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MEMORANDUM OPINION

NOVEMBER 9, 2018

CONNOLLY, UNITED STATES DISTRICT JUDGE

Presently before me are competing filings regarding the Amended Recommendation and Report (D.I. 108) (the "Recommendation and Report") issued by the Special Master appointed by the previously assigned judge to this case, the now retired Honorable Gregory M. Sleet. Defendants Actavis Elizabeth LLC, Actavis Pharma, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. (collectively, "Actavis") have filed objections to the Recommendation and Report. D.I. 113. Plaintiffs Orexo AB and Orexo US, Inc. (collectively, "Orexo") have filed a motion to adopt the Recommendation and Report. D.I. 115. I have studied the Recommendation and Report (D.I. 108), the parties' briefing submitted to Judge Sleet (D.I. 14, 22, 24, 113, 115, 130, 131, 134, 135), the parties' submissions to the Special Master (D.I. 113 Ex. C, D.I. 131 Ex. B, D.I. 155), a transcript of the February 7, 2018 hearing before the Special Master (Tr. of Feb. 7, 2018 Hr'g), and 29 privileged documents submitted by Orexo for the Special Master's *in camera* review (D.I. 155). For the reasons discussed below, I will overrule Actavis's objections and adopt the Recommendation and Report.

I. BACKGROUND

Orexo alleged in its complaint that Actavis's generic versions of Suboxone® and Subutex® infringe United States Patent No. 8,454,996 ("the #996 patent"). In an earlier case filed in this court, Orexo had alleged that Actavis Elizabeth LLC's generic version of Zubsolv® infringed the #996 patent. *Orexo AB v. Actavis Elizabeth LLC,* 217 F. Supp. 3d 756 (D. Del. 2016) (the "Zubsolv litigation"). After a bench trial in the Zubsolv litigation, the now retired Honorable Sue L. Robinson ruled among other things that the #996 patent was valid and infringed by Actavis Elizabeth LLC's generic version of Zubsolv®. *See id.* at 776–81. Actavis Elizabeth LLC did not appeal Judge Robinson's rulings with respect to the #996 patent.[1]

Shortly after Orexo filed its complaint in this matter, Actavis filed a motion to strike and dismiss. D.I. 13. In its brief filed in support of the motion, Actavis argued that Orexo's allegations in its complaint about Actavis's generic versions of Suboxone® and Subutex® were "derived" from confidential information Actavis

[1] In the Zubsolv litigation, Judge Robinson also held that U.S. Patent No. 8,940,330 ("the #330 patent") was invalid as obvious. *Orexo AB*, 217 F. Supp. 3d at 769–76. Orexo appealed Judge Robinson's ruling with respect to the #330 patent and the Federal Circuit reversed, holding that Actavis Elizabeth LLC did not establish obviousness by clear and convincing evidence. *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1274 (Fed. Cir. 2018). The Federal Circuit's decision to reverse Judge Robinson's decision with respect to the #330 patent does not implicate Judge Robinson's rulings with respect to the #996 patent.

Elizabeth LLC had produced in the Zubsolv litigation pursuant to a protective order which provided that Orexo could "use [such confidential information] solely for purposes of assisting Outside Counsel in connection with" the Zubsolv litigation. D.I. 14 at 2 (quoting protective order). In Actavis's words, "Orexo appears to have 'use[d]' that confidential information in this case in violation of the Protective Order." *Id.* at 5 (alteration in original). Actavis based its conclusion that "Orexo appears to have" violated the Zubsolv litigation protective order on the fact that Orexo filed its complaint in this action in February 2017 — four years after the launch of Actavis's generic Suboxone® and two years after the launch of its generic Subutex®. Actavis further argued that "[c]ritically, Orexo waited until after the [#]996 patent was held valid in the Zubsolv® [l]itigation, and Actavis [Elizabeth LLC] had chosen not to appeal." *Id.*

Judge Sleet appointed the Special Master "for the purpose of resolving" Actavis's "allegation that Orexo improperly used confidential information produced under a protective order in [the Zubsolv litigation] in connection with the allegations in the complaint in this action." D.I. 38 at 1. In the five-page appointment order, Judge Sleet directed the Special Master to issue a report to the Court addressing the following questions:

1. Did Orexo impermissibly "use" Actavis confidential information to support the complaint in this action?

2. Did [Actavis] meet [its] burden of proof to show that the protective order in the [Zubsolv] litigation was violated?

3. If there was a violation, identify the violation.

4. Such other questions that may arise that the Special Master deems pertinent to the dispute to be addressed.

Id. at 2.

The Special Master reviewed the parties' extensive briefing on Actavis's motion to strike and dismiss and, consistent with Judge Sleet's appointment order, offered the parties the opportunity to "provide any submissions and/or declarations [they] deemed helpful." D.I. 108 at 7. Also consistent with Judge Sleet's appointment order, Orexo submitted and the Special Master reviewed declarations from Orexo's Head of Pharmaceutical Development and Intellectual Property and from Orexo's lead outside counsel in the Zubsolv litigation; privileged emails and correspondence regarding the acquisition, testing, and analyses of Actavis's generic versions Suboxone® and Subutex®; and documents in which Orexo and its lawyers evaluated potential litigation and analyzed patent infringement claims and potential legal defenses to such claims. *Id.* at 8.

After reviewing these materials and hearing oral argument from the parties, the Special Master issued his Recommendation and Report. The Special Master found that "[t]here is no basis to conclude there was any violation" of the

protective order issued in the Zubsolv litigation and recommended that the Court deny Actavis's motion to strike and dismiss. D.I. 108 at 24.[2]

II. STANDARD OF REVIEW

Rule 53(f) of the Federal Rules of Civil Procedure permits the Court to "adopt or affirm, modify, wholly or partly reject or reverse, or resubmit" a special master's report or recommendation. Fed. R. Civ. P. 53(f)(1). The Court reviews *de novo* the Special Master's legal conclusions. Fed. R. Civ. P. 53(f)(4). Where, as here, the parties have not stipulated to the contrary, the Court also reviews the Special Master's factual findings *de novo*. Fed. R. Civ. P. 53(f)(3). The Special Master's procedural rulings are reviewed for abuse of discretion. Fed. R. Civ. P. 53(f)(5).

III. DISCUSSION

Actavis raises three objections to the Recommendation and Report. It contends that the Recommendation and Report reached a "flawed conclusion only because it [(1)] [did] not recognize the true implication of its own factual findings, [(2)] is based on an incomplete record, and [(3)] contains several factual inaccuracies." D.I. 113 at 1. In its answering brief filed in opposition to Orexo's

[2] Although the Special Master was not expressly directed to recommend how the Court should rule on Actavis's motion, the motion is premised on a factual determination that Orexo violated the Zubsolv litigation protective order, and the Special Master was explicitly directed by Judge Sleet to determine whether Actavis met its burden to establish that this factual predicate had occurred.

motion to adopt the Recommendation and Report, Actavis argues additionally that the deposition of Orexo's corporate representative witness, Dr. Robert Rönn, "emphasizes the inconsistencies" in Orexo's arguments and the Special Master's Recommendation and Report.[3] D.I. 130 at 7. I discuss these arguments in turn.

A. The "True Implication" of The Special Master's Factual Findings

It has never been disputed (and, not surprisingly, the Special Master found as a factual matter) that Orexo was aware of Actavis's generic versions of Suboxone® and Subutex® in 2013 but did not file this suit until February 2017. *See* D.I. 131 at 5. The crux of both Actavis's motion to strike and dismiss and its objections to the Recommendation and Report is that "the only reasonable conclusion" to be drawn from Orexo's delay in bringing the present action is that Orexo's outside counsel improperly used confidential information obtained under the protective order. *See* D.I. 113 at 1.

As an initial matter, I reject the logic of Actavis's argument. While Orexo's three-year delay in bringing this case might invite speculation that the allegations in its complaint were derived from confidential information obtained in the Zubsolv litigation, it is simply not the case that Orexo's improper use of that information is the only rational explanation for Orexo's decision to file this suit in

[3] The deposition occurred after the Special Master issued the Recommendation and Report. D.I. 130, Ex. A.

February 2017. On the contrary, given (1) the costs and risks associated with patent litigation,[4] (2) Judge Robinson's ruling in the Zubsolv litigation that the #996 patent was valid, and (3) Orexo's counsel's reasonable conclusion that Actavis Elizabeth LLC could be collaterally estopped from challenging the validity of the #996 patent in this litigation, it was perfectly reasonable for Orexo's counsel to suggest in the wake of the Zubsolv litigation that Orexo consider obtaining and testing generic Suboxone® samples and, depending on the outcome of the testing, filing this action.

Second, having reviewed carefully the documents submitted to the Special Master, including Orexo's privileged documents, I agree with the Special Master's finding that "[t]here is no basis to conclude [that] there was any violation" of the Zubsolv litigation protective order. The evidentiary record establishes (1) that Orexo had general concerns in 2013 that Suboxone® infringed the #996 patent; (2) that Orexo first became profitable in 2016 and that its lack of financial resources before that date resulted in a strategic choice to focus its resources solely on the launch of Zubsolv® and the related Zubsolv litigation; and (3) that Orexo's

[4] Recent data from the American Intellectual Property Law Association's 2017 Report of the Economic Survey shows that the median overall cost to litigate a patent infringement case with $1 million to $10 million at stake is $1.7 million. Malathi Nayak, *Cost of Patent Infringement Litigation Falling Sharply*, BLOOMBERG BNA (Nov. 7, 2018, 10:48 AM), https://www.bna.com/cost-patent-infringement-n73014463011/.

enhanced financial situation and its counsel's reasonable conclusion that Actavis Elizabeth LLC would be collaterally estopped from challenging the #996 patent's validity following the Zubsolv litigation explain both Orexo's decision in 2017 to file the present action and its decision not to bring infringement actions against other generic manufacturers of Suboxone® and Subutex®. *See* Tr. at 40:12-42:20; Taylor Dec. at ¶¶ 8–17, 29; D.I. 135 Ex. B, Rönn Dec. at ¶¶ 8-11; D.I. 135 Ex. E, Tr. of July 18, 2018 Sørensen Deposition at 4:6-5:4, 57:19-59:18, 61:18-62:9; D.I. 155. I find in short that the documents in the record and the declarations of Orexo's outside counsel and Orexo's Head of Pharmaceutical Development and Intellectual Property negate Actavis's allegation that Orexo used confidential information from the Zubsolv litigation to bring the present action.

B. The Completeness of The Record

Actavis also contends that the Special Master never ruled on Actavis's request to compel Orexo to produce additional privileged documents for *in camera* review. D.I. 113 at 6–9. But in fact the Special Master explicitly noted in his Recommendation and Report that Actavis had alleged in its October 20, 2017 letter to the Special Master that "the information provided [by Orexo] for *in camera* inspection did not provide a sufficient basis to decide whether the protective order entered by Judge Robinson had been violated" (D.I. 108 at 16), and he expressly ruled to the contrary that "the information and argument provided [by the parties]

is sufficient to respond to the questions raised by Judge Sleet his October 10, 2017 order [appointing the Special Master]." *Id.* at 17. In any event, having reviewed the privileged materials submitted by Orexo, I find that there is no need to require further production of documents from Orexo.

C. The Accuracy of The Special Master's Factual Findings

Actavis objects to three putative factual findings made by the Special Master. D.I. 113 at 9-11. First, Actavis takes issue with the Special Master's statement that Actavis "'fail[ed] to specify and/or identify what confidential information was provided and therefore protected.'" *Id.* at 9 (quoting D.I. 108 at 20). I have doubts that this statement is properly characterized as a factual finding. But, in any event, while I agree with Actavis that it had identified its dry mixing manufacturing process as a specific example of the confidential information it alleged Orexo had obtained in the Zubsolv litigation, *see id.* at 10, I find that the Special Master's erroneous statement is of no consequence, because (1) nothing in the record suggests that Orexo used that manufacturing information in deciding whether to file suit or in drafting its complaint; (2) Orexo's outside counsel in both the Zubsolv litigation and this action denied under oath that such confidential information was used in determining whether to file this suit or in drafting the complaint, *see* Taylor Dec. at ¶ 6; and (3) definitive knowledge of Actavis's manufacturing process was not a prerequisite to filing the complaint in this action,

see Hoffmann-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1363–65 (Fed. Cir. 2000).

Second, Actavis challenges the Special Master's description of crospovidone — an ingredient in Actavis's generic Suboxone® and generic Subutex® products — as a bio/mucoadhesive, which is a claim limitation of the #996 patent. D.I. 113 at 11. In my view, however, the Special Master's factual findings in this regard are better read as summarizing Orexo's belief about Actavis's generic products. I do not read the Recommendation and Report as including factual findings that crospovidone is a bio/mucoadhesive and that the presence of crospovidone in Actavis's generic versions of Suboxone® and Subutex® infringes the #996 patent. When read in the context of the entire Recommendation and Report, the findings concern Oerexo's beliefs, and they are consistent with Orexo's stated rationale for bringing the present patent infringement action against Actavis.

Third, Actavis argues that the Recommendation and Report incorrectly "states that Actavis's generic Suboxone® products are 'more similar [to] Zubsolv' than to brand Suboxone®" and that "[r]elatedly, the [Recommendation and Report] implies that Actavis's generic Suboxone® products are similar to Zubsolv® in order to differentiate Orexo filing suit against Actavis while not filing suit against Amneal, which manufactures a generic Suboxone® product 'nearly identical to the brand name Suboxone.'" D.I. 113 at 11-12 (quoting D.I. 108 at 10). The sentence

in the Recommendation and Report to which Actavis objects reads: "Additional analysis revealed that Amneal's generic Suboxone was nearly identical to the brand name Suboxone while [Actavis's] generic was not but more similar to Zubsolv." D.I. 108 at 10. I am not exactly sure what the Special Master intended to communicate in this sentence, but it is clear from the sentences that precede this sentence in the Recommendation and Report and the supporting documentation submitted to the Special Master by Orexo that the "additional analysis" to which the Special Master refers occurred in 2013 and 2014. As I have already noted, the record evidence establishes that Orexo was not profitable until 2016 and that Orexo understandably focused its resources in 2013 and 2014 on the launch of Zubsolv® and the related Zubsolv litigation against Actavis Elizabeth LLC. Accordingly, the Special Master's statement has no bearing on my decision.

Actavis may be correct that the Special Master was trying to "differentiate Orexo filing suit against Actavis while not filing suit against Amneal" (D.I. 113 at 12), but that, too, is of no consequence. Actavis argues that "Orexo's proffered explanation for investigating Actavis's product, but not Amneal's [product] makes no sense." *Id.* at 12. But Orexo's explanation for investigating — **in 2016 (not 2013 or 2014)** — Actavis's product as opposed to Ameal's product makes a lot of sense. Amneal was not a party to the Zubsolv litigation and therefore could not be bound by Judge Robinson's ruling that the #996 patent was valid. Actavis

Elizabeth LLC, however, was a party to the Zubsolv litigation; and Orexo's counsel reasonably believed that it would be bound by Judge Robinson's ruling.

D. Dr. Robert Rönn's Deposition

Finally, Actavis argues that the Recommendation and Report should not be adopted because of testimony Actavis elicited at the deposition of Orexo's corporate witness, Dr. Rönn, after the Special Master issued the Recommendation and Report. *See* D.I. 130 at 2. Actavis alleges that Dr. Rönn's testimony contradicted Orexo's argument that Orexo suspected infringement back in 2013 but lacked the resources at that time to bring a patent infringement action based on Actavis's generic Suboxone®. *Id.* at 1. The testimony Actavis cites is this:

> Q: What non-privileged information can you share underlying Orexo's decision not to bring suit, in this case, prior to February 2017?
> A: Orexo didn't have the resources to do it.
> * * * *
> Q: I understand that Zubsolv litigation consumed resources. I'm trying to understand your answer. Are you saying that because Orexo was actively involved in of the Zubsolv litigation, that's why it did not have the resources to bring this lawsuit at that time during the Zubsolv litigation?
> A: Well, yes, during the Zubsolv litigation.
> Q: So if the Zubsolv litigation had not been going on, then Orexo would have had the resources to bring this lawsuit earlier; is that correct?
> A: I don't know that.
> Q: Well, I'm trying to get a sense whether the Zubsolv litigation, the fact that that was going on, had any bearing in the availability of Orexo's resources to bring this case; did it?

> A: I mean, again — I mean the Zubsolv litigation consumed resources for Orexo. ***So but part from that would be me speculating. I don't know this is hypothetical question to me that I can't really answer.***

Id. at 7 (emphasis in original) (quoting D.I. 135 Ex. D, Tr. of July 7, 2018 Rönn Deposition at 76:20-78:21). Actavis argues that "Dr. Rönn's answer emphasizes the inconsistencies in Orexo's whole story[] . . . that Orexo lacked the resources to investigate Actavis's products when it first became aware of those products" in 2013. *Id.* at 7.

I disagree. Dr. Rönn's "I don't know" answer to a hypothetical question is entirely appropriate and does not contradict or call into question his earlier testimony (given in response to non-hypothetical questions) that "Orexo didn't have the resources to [bring this suit] . . . during the Zubsolv litigation." I agree with Orexo that "knowing that you could not bring a lawsuit because you lacked resources is not the same thing as knowing what would have happened if you [had] had more resources." D.I. 135 at 6.

IV. CONCLUSION

For the reasons discussed above, I will overrule Actavis's objections (D.I. 113) and grant Orexo's motion to adopt the Special Master's Recommendation and Report (D.I. 115).

The Court will issue an order consistent with this Memorandum Opinion.